

## **REMARKS**

### **I. Explanation of Amendments**

New claim 79 finds support throughout the application, including at page 3, lines 16-29, page 14, lines 10-12, page 51, lines 18-29 and page 53, lines 16-22.

Claims 1-2, 4, 11-12, 15, 22, 26, 28-29, 31, 68 and 74 have been amended to recite “Prox-1 expression or activity.” Support for these amendments can be found throughout the application, including at page 10, lines 1-9, page 15, lines 3-14 and page 33, lines 22-26.

### **II. Election**

The Applicants elect Group I, the method of screening colon tissue for a pathological condition via measuring Prox-1 protein expression, for examination in the above-identified application. Applicants further elect the species of claim 12, the Beta-catenin/TCF signaling pathway, and the species of claim 13, nuclear localization of Beta-catenin, for examination in the above-identified application.

The Applicants agree with the U.S. Patent and Trademark Office that claims 1-6 and 12-15 are drawn to the elected invention insofar as they specifically refer to (or are generic with respect to) a method of screening colon tissue for a pathological condition via measuring Prox-1 expression or coordinated Beta-catenin/TCF signaling pathway activation and Prox-1 expression.

The restriction requirement at page 8 purports to outline additional species elections with respect to Group I relating to antisense nucleic acids, but these are apparent typographical errors, because Group I does not pertain to antisense methods.

### **III. Traversal of restriction requirement**

The Applicants traverse the restriction requirement. It is premised on and characterized as lack of unity, but no proper unity analysis was performed.

Unity analysis traditionally involves presence/absence of a novel technical feature unifying the claims. See 37 CFR 1.475(a). Here, a common and novel technical feature, as noted by the EPO (see quotation below) during the international phase of this application, is the elevated expression or involvement of Prox-1 in colorectal cancer. This technical feature unifies all of the pending claims:

**In contrast, claims 1-45 and 67-78 appear to fulfill the requirements of Article 33(3) PCT, because the prior art does not seem to disclose the correlation between elevated Prox-1 expression and colorectal cancer. Therefore, the skilled person would have no incentive (I) to screen colon tissue for colorectal cancer by measuring Prox-1 overexpression (claims 1-15); or (II) to inhibit the growth of colorectal cancer cells by suppressing Prox-1 expression/activity (claims 17-31, 33-34, 36-38, 40-41, 43-45, 74-76, and 78). Analogous arguments apply to the use of molecules suppressing Prox-1 expression/activity in the manufacture of medicaments for the treatment of colorectal cancer (claims 16, 18-30, 32, 35-37, 39-40, 42-45, 67-75, and 77-78).**

The claims of at least Groups I and II share the **additional common technical feature recited in claim 1**, for example, relating to a method of screening colon tissue for a pathological condition via measuring Prox-1. The fact that some of the *dependent* claims specify different *methods of measuring* Prox-1 does not change the fact that claims 1-15 have unity. The additional technical feature of using Prox-1 as a diagnostic-type marker, in the manners described in the specification, unifies Groups I and II.

Finally, it is worth observing that claim 15 links Groups I and II with Groups III-VI.

In the restriction requirement, there was no analysis of whether the claims share a common and novel technical feature. Rather, the Patent Office's analysis appears to have skipped Rule 1.475(a) entirely and jumped directly to an analysis of 37 CFR 1.475(b). (See restriction requirement at p. 4.)

Even Rule 1.475(b) counsels **against** the division of Groups I and II in this case (and against the division of Groups III-VI), because the claims of Groups I and II are directed to a single category of invention (diagnostic methods). Rule 1.475(b) only provides guidance as to when *product and process* claims (separate classes of invention) should be

divided from each other and when they should not. There is nothing in Rule 1.475(b) that suggests diagnostic method claims should be divided from each other, into multiple groups, or more generally that method claims with a common technical feature should be divided.

For all of these reasons, the restriction requirement was improper, and should be withdrawn.

#### IV. Conclusion

In view of the foregoing amendments and remarks, Applicants request prompt and favorable review of all pending claims.

Applicant submits this response together with a petition for a four month extension of time and appropriate fees. However, should the Examiner determine that additional fees are due, please charge our Deposit Account No. 13-2855, under Order No. 28113/39467A from which the undersigned is authorized to draw.

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Respectfully submitted,

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